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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,902	12/16/1999	WILLIAM C. OLSON	57906-AJPW/S	8227

7590 10/21/2005
COOPER & DUNHAM LLP
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NEW YORK, NY 10036

EXAMINER

LE, EMILY M

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/464,902

Applicant(s)

OLSON ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005 and 18 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 110-137 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 110-137 is/are rejected.
- 7) ☒ Claim(s) 116-124, 127-130 and 133-137 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/29/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/18/2005 has been entered.

Status of Claims

2. Claims 1-109 are cancelled. Claims 110-137 are added. Claims 110-137 are pending and under examination.

Claim Objections

3. Claims 116-124, 127-130 and 133-137 are objected to because of the following informalities: The claims recite the recitations "an antibody" and/or "single chain antibody". The recitations are objected to because it appears that the cited recitations do not directly refer back to the antibody recited in the independent claim.

To obviate this objection, the Office suggests Applicant to amend the recitation "an antibody" to "said antibody", and the recitation "single chain antibody" to "the single chain of said antibody".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 110-137 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to an isolated nucleic acid encoding a polypeptide comprising three CDR regions of one of six listed antibodies, wherein said polypeptide binds to an epitope of CCR5 when combined with a second polypeptide.

The instant written rejection is directed at the second polypeptide. In the instant, the specification only disclosed of one species of second polypeptide per listed antibody. However, the claims are directed to a genus of second polypeptides.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient description of a representative number of species by i) actual reduction to practice, ii) reduction to drawings, or iii) disclosure of relevant identifying characteristics. Examples of factors to be considered for the latter requirement include:

- disclosure of complete or partial structure,
- physical and/or chemical properties,
- functional characteristics,
- correlation between structure and function, and

- methods of making.

Each of the listed criteria is addressed in turn below.

i) sufficient description of a representative number of species by actual reduction to practice: As provided above, only one species among a multitude of species is inherently, via the possession of the antibody, disclosed in the specification. A disclosure of only one species among the multitude of species that can possibly be envisioned is not a sufficient description of a representative number of species by actual reduction to practice.

ii) sufficient description of a representative number of species by reduction to drawings: The drawings do not provide a description of any species that is encompassed by the recitation "second polypeptide". Thus, the drawings do not provide a sufficient description of a representative number of species by actual reduction to practice.

iii) sufficient description of a representative number of species by disclosure of relevant identifying characteristics:

- disclosure of complete or partial structure: The specification does not provide either a complete or partial structure of the second polypeptide. As noted above, the disclosure on provides an inherent teaching of the one species that is encompassed by the recitation "second polypeptide".
- physical and/or chemical properties: Neither the claims nor the specification require the second polypeptide to have a particular physical and/or chemical property.

- functional characteristics: The claims require that the second polypeptide, when used in conjunction with the first polypeptide, binds to an epitope on CCR5. However, this is not a functional characteristic that is exclusive of the second polypeptide. It is a functional characteristic that is expected when the first and second polypeptide are used in combination with one another. Thus, no functional characteristic for the second polypeptide is provided in the claims. Nor is one provided for the second polypeptide in the specification.
- correlation between structure and function: No correlation between structure and function can be rendered from the specification.
- methods of making the second polypeptide: A method of making generic polypeptides is well known in the art; however, without a correlative teaching between structure and the required functional characteristics, the skilled artisan would not be able to envisage the second polypeptide. Thus, a method of making a second polypeptide having a functional characteristic, when combined with the first polypeptide, is not readily apparent.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that

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[he or she] invented what is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of second polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the one species of second polypeptides for each of listed antibodies, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

To overcome the instant rejection, the Office suggests that Applicant amends the recitation “wherein the polypeptide in combination with a second polypeptide” to “wherein the polypeptide in combination with a heavy/light chain of an anti-CCR5 antibody”.

Conclusion

6. No claim is allowed.

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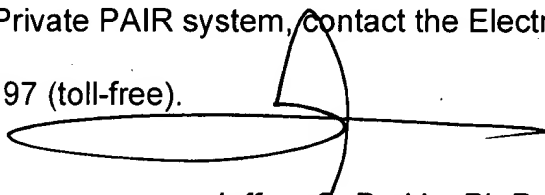
7. The claims would be allowable if Applicant adopts the suggestions provided herein.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be "Jeffrey S. Parkin", written over a horizontal line.

Jeffrey S. Parkin, Ph.D.
Primary Patent Examiner
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A handwritten signature in black ink, appearing to be "Emily Le", written over a horizontal line.
E. Le